

DEPARTMENT OF HEALTH & HUMAN SERVICES



Healthcare Systems Bureau Rockville, MD 20857

DATE: September 8, 2020

TO: Josh Brammer, OMB Desk Officer

FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) Data and

Evaluation Division requests approval for non-substantive changes to the

2020 Uniform Data System (UDS) Collection (OMB 0915-0193

expiration date 02/28/2023).

Purpose: The purpose of this request is to make changes to Table 6A and Table 9E,

and corresponding changes to the UDS Manual, to capture data on COVID-19 testing, vaccine administration and financial data related to relief funding passed by Congress in response to the pandemic. Collection of this information will help HRSA track health center capacity and the impact of COVID-19 on health centers, and is essential to better understanding training and technical assistance, funding, and other resource needs for this and future public health emergencies. This memo

explains the changes and supporting rationale.

Table 6A is being updated to include new diagnostic codes. The Centers for Disease Control and Prevention (CDC) released COVID-19 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10) codes¹ and the American Medical Association released COVID-19 Current Procedural Terminology (CPT) codes² to streamline COVID-19 testing and diagnosis reporting in the U.S as well as codes for acute respiratory illness due to COVID-19. Since these items were approved in April of this year, new codes have been created and existing codes have been updated with new information. To be more responsive to the pandemic, we also need to update our data collection to reflect these changes. Specifically, we are requesting to add additional clinical codes and update the values in Table 6A.

To date, there are eight COVID-19 vaccines in Phase 3 clinical trials and more than 160 vaccines in various clinical trial stages ranging from pre-

¹ https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf

² https://www.ama-assn.org/practice-management/cpt/covid-19-coding-and-guidance

clinical to Phase 2; there are two COVID-19 vaccines that have been approved in China and Russia.³ HRSA is tracking the development of a vaccine in the U.S. and any associated clinical codes; at this time, no clinical codes exist. Given the resources and attention being put into vaccine development, HRSA is being proactive and requesting to include a question in Appendix E—Other Data Elements of the UDS to be able to capture the amount of patients that receive a vaccine in 2020, should one be approved and distributed across the country. Requesting this change now will ensure HRSA has enough time to code and build this question into our UDS data collection systems. Specifically, we are requesting to include a question on how many patients were administered an FDA approved COVID-19 vaccine during the calendar year2020.

Table 9E requires modification to allow for additional granularity in pandemic relief funding. As part of the historic U.S. response to the Coronavirus Disease 2019 (COVID-19) pandemic, health centers were awarded supplemental funding to prevent, prepare for, and respond to the pandemic. In July 2020, the Paycheck Protection Program and Health Care Enhancement Act was passed and HRSA provided \$583 million in Expanding Capacity for Coronavirus Testing (ECT) and \$17 million was provided to Look-Alikes (LAL ECT). In order to track these supplemental funds, additional rows need to be included in Table 9E.

Currently, there are additional relief bills that Congress is proposing⁴. To prepare for the outcome of this legislation, HRSA is requesting the ability to include additional rows to capture these pending funding sources. Specifically, we are requesting to add two additional lines to track COVID-19 funding under the H8E activity code and the Health and Economic Recovery Omnibus Emergency Solutions Act (HEROES)/ Health, Economic Assistance, Liability Protection and Schools Act (HEALS) legislation that is being deliberated in Congress.

The overall scope of change in data collected for the 2020 UDS is minimal, representing an update of existing content. Given the unprecedented nature of the pandemic and the response of health centers to address this crisis, we feel these changes are necessary.

³ https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

⁴ https://www.congress.gov/bill/116th-congress/house-bill/6800, https://www.congress.gov/bill/116th-congress/senate-bill/1624/all-info

Time Sensitivity: The UDS data collection changes must be completed in a timely manner to

fulfill Health Center Program requirements. Approval of these changes is needed by September 9, 2020, to implement the changes in the data collection system and to provide guidance to health centers for how to

properly report this timely and critical information to HRSA.

Burden: The non-substantive changes included herein do not substantially change

the estimated reporting burden for health centers. Making these changes will allow health centers to accurately capture the services they are

providing in the midst of the pandemic response.

PROPOSED CLARIFICATIONS AND NON-SUBSTANTIVE CHANGES FOR UNIFORM DATA SYSTEM FORMS:

Table 6A

a. Line 21c and 21d – Updates

Adding additional novel coronavirus (SARS-CoV-2) testing CPT-4 and CPT PLA codes: 87426, 86408, 86409, 0202U, 0223U, 00225U, 0224U, and 0226U

<u>Rationale</u>: In response to the pandemic, many health centers have created testing sites. These codes would allow HRSA to monitor how health centers have served their communities and patients, providing a better understand training and technical assistance, funding, and other resource needs around testing for COVID-19.

Table 9E

b. 1n, 10 – Additions

Two new rows to capture more detail on funding provided to health centers during the pandemic

<u>Rationale</u>: These additional lines would allow HRSA to track Expanding Capacity for Coronavirus Testing (ECT) and the pending HEROES/HEALS legislation and any subsequent supplemental funding.

Attachments:

- 1. 2020 UDS Manual-proposed changes. All changes highlighted in yellow are additions to the attached document.
- 2. 2020 UDS Tables-proposed changes. All changes highlighted in yellow are additions to the attached document.